UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/583,334	03/07/2007	Francesco Santangelo	U 016325-6	9753

140 7590 01/06/2012

LADAS & PARRY LLP
1040 Avenue of the Americas
NEW YORK, NY 10018-3738

EXAMINER	
SPIVACK, PHYLLIS G	
ART UNIT	PAPER NUMBER
1629	

NOTIFICATION DATE	DELIVERY MODE
01/06/2012	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

nyuspatactions@ladas.com
nymail@ladas.com

Office Action Summary	Application No.	Applicant(s)	
	10/583,334	SANTANGELO, FRANCESCO	
	Examiner	Art Unit	
	PHYLLIS G. SPIVACK	1629	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 October 2011*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.

4)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

5)☒ Claim(s) *3 and 10* is/are pending in the application.

5a) Of the above claim(s) _____ is/are withdrawn from consideration.

6)☐ Claim(s) _____ is/are allowed.

7)☒ Claim(s) *3, 10* is/are rejected.

8)☐ Claim(s) _____ is/are objected to.

9)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

10)☐ The specification is objected to by the Examiner.

11)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

12)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Applicant's Response filed October 2, 2011 is acknowledged. Claims 3 and 10 remain under consideration.

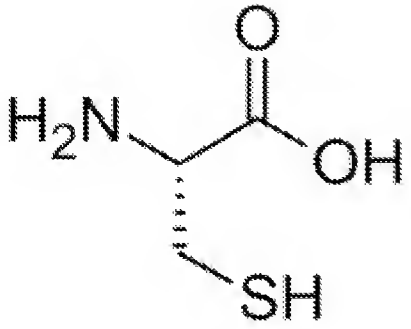
A new title is noted.

Claims 3 and 10 were rejected under 35 U.S.C. 103(a) in the last Office Action, as being unpatentable over Galli et al., Nephrology, Dialysis, Transplantation, in view of Zaloga et al., U.S. Patent 6,060,446, and further in view of Droge et al., U.S. Patent 5,607,974. It was asserted in patients undergoing hemodialysis with end-stage renal disease, apoptosis, thiol loss in the peripheral blood mononuclear leukocytes and oxidative stress are significant findings. Galli broadly teaches the administration of exogenous antioxidants to restore a deficit of intracellular thiols. See the Abstract. Galli does not teach the specific administration of cysteine. However, Zaloga teaches the administration of cysteine, as a nutrient, to treat renal failure. See column 4, lines 32-40, where cysteine is characterized as a scavenger of oxygen free radicals, as a substance that reduces renal cellular injury and as a precursor for the antioxidant compound glutathione. Cysteine is also described as cytoprotective in column 5, line 36. Oral administration is disclosed in column 6, line 44. Zaloga urges the need for dialysis may be decreased following administration of the nutritional composition of his invention. Droge teaches the oral administration of tablets for countering cysteine deficiency having about 100 mg to 1 gm to patients receiving hemodialysis. See column 2, line 14, as well as column 3, lines 14-19.

Applicant argues Galli does not suggest the oral administration of cysteine or cysteine, and Zaloga seems to require the administration of a mixture of amino acids but without reference to hemodialysis. Applicant states Droge teaches patients having a cysteine deficiency may beneficially be treated with a cysteine source that is capable of being transported across the cellular membrane without listing cysteine. Droge, in Applicant's view, is seeking to insert cysteine into liposome lumens so that it can result in an increase in the thiol level in blood plasma.

Applicant's arguments have been given careful consideration but are not found persuasive. The rejection of record of claims 3 and 10 under 35 U.S.C. 103 is maintained. It is noted the oral administration, as recited in instant claim 10, is in the alternative, i.e., the administration is of cysteine or cystine or a mixture thereof.

Galli's teaching is directed to hemodialysis patients in whom a multifactorial impairment of immune function and oxidative stress are commonly diagnosed. Galli suggests conditions of oxidative stress could play a key role in the increased apoptotic (programmed cell death) rate in hemodialysis patients. According to Galli, these patients exhibited a 40% decrease in the intracellular pool of thiols, which accompany the accelerated apoptosis, and the exogenous administration of antioxidants, such as thiol suppliers, of which cysteine and cysteine are examples, could be used to down-regulate apoptosis.

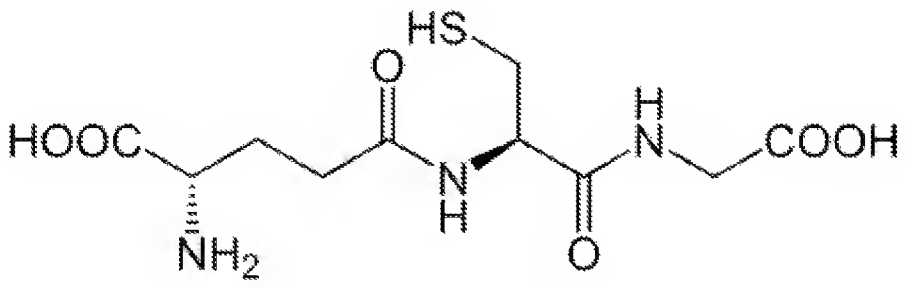


cysteine

Cystine is a dimeric amino acid formed by the oxidation of two cysteine residues that covalently link to make a disulfide bond.

See line 9, column one, page 1599, where Galli describes "a critical cysteine residue" is known to provide its anti-apoptotic function through an anti-oxidant-like mechanism mediated through perturbations of intracellular thiols. See the last sentence of column one on page 1600, where Galli states his results highlight the potential role of anti-oxidant-based strategies to constrain abnormal apoptosis in leukocytes of chronic hemodialysis patients.

Ross et al., American Journal of Kidney Diseases, (Abstract), is presented as further evidence that hemodialysis patients exhibit acutely lowered cysteine levels compared to controls. According to Ross, hemodialysis patients are at increased risk from oxidative stress due to glutathione deficiency in blood cells. The sulfhydryl (thiol) group (SH) of cysteine serves as a proton donor and is responsible for the biological activity of glutathione. Glutathione is a tripeptide consisting of glutamate, cysteine and glycine.



glutathione

Therefore, one skilled in the renal art would have been motivated to administer cysteine orally to a patient undergoing hemodialysis in order to treat oxidative stress from the procedure. Such administration would have been obvious because cysteine qualifies as a "thiol supplier," as described by Galli and Ross. Zaloga establishes the administration of cysteine to treat renal failure. See column 4, lines 32-40, where cysteine is characterized as a scavenger of oxygen free radicals, as a substance that reduces renal cellular injury and as a precursor for the antioxidant compound glutathione. Droge is included in the rejection only to teach the oral administration of tablets for countering cysteine deficiency and for elevating plasma thiol levels. See column 2, line 14. An amount of about 100 mg to 1 gm to patients receiving hemodialysis is disclosed in column 3, lines 14-19.

No claim is allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this Final Action is set to expire THREE MONTHS from the mailing date of this Action. In the event a first reply is filed within TWO MONTHS of the mailing date of this Final Action and the Advisory Action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the Advisory Action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the Advisory Action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this Final Action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phyllis G. Spivack whose telephone number is 571-272-0585. The Examiner can normally be reached on 10:30 AM-7 PM.

If attempts to reach the Examiner by telephone are unsuccessful after one business day, the Examiner's supervisor, Jeff Lundgren, can be reached on 591-272-5541. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

December 30, 2011

/Phyllis G. Spivack/
Primary Examiner, Art Unit 1629